UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/620,149	07/14/2003	Christopher J. Savoie	2501437-991010	8496

7590 06/29/2005

Nan Wu, M.D., Ph.D, J.D.
MORGAN, LEWIS & BOCKIUS LLP
One Market Street,
Spear Street Tower
San Francisco, CA 94105

EXAMINER	
KELLY, ROBERT M	

ART UNIT	PAPER NUMBER
1633	

DATE MAILED: 06/29/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/620,149	SAVOIE ET AL.	
	Examiner	Art Unit	
	Robert M. Kelly	1632	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *1* MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *18 April 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-40* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-40* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Applicant's response of 4/18/05 has been entered; however, the restriction requirement of 11/29/05 is now withdrawn in favor of the following restriction requirement.

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-10, drawn to methods of affecting or increasing antifungal activity in a system, classified in class 435, subclass 184.

II. Claims 11-12, drawn to a database comprising a plurality of target genes, classified in class 707, subclass 100.

III. Claims 13-18 and 21-23, drawn to isolated polynucleotides comprising a partial sequence of a target gene and vectors and genes comprising the polynucleotides, classified in class 536, subclass 23.1.

IV. Claims 19 and 24, drawn to polypeptides, classified in class 530, subclass 350.

V. Claims 20, drawn to antibodies that modulate activities of specific proteins, classified in class 530, subclass 387.1.

VI. Claims 27 and 30, drawn to a system comprising a plurality of polypeptides and allowing for parallel analysis, classified in class 435, subclass 4.

VII. Claims 25-26 and 28-29, drawn to a system comprising a plurality of polynucleic acids allowing for parallel analysis, classified in class 435, subclass 6.

VIII. Claims 31-39, drawn to a screen for candidate antifungal agents, classified in class 435, subclass 32.

IX. Claim 40, drawn to an antifungal agent, classified in class 536, subclass 16.8.

The inventions are distinct, each from the other because of the following reasons:

The compositions of inventions II-VII and IX, are patentably distinct. Inventions are patentably distinct if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are not disclosed as capable of use together and have different structural requirements and functions therefrom which are not coextensive and provide for different effects. Group II, drawn to a database requires a symbolic listing of target genes and relationships, Group III requires a polynucleotide sequence, which may be used to make protein, but may also be used for hybridization assays, Group IV, drawn to polypeptides, have enzymatic functions and may be used to treat disease, Group V, drawn to antibodies that inhibit certain polypeptides, may be used to inhibit those polypeptides or in methods of detection, Group VI, drawn to a system with a plurality of polypeptides and allowing for parallel analysis requires structure to analyze multiple polypeptides independently, Group VII, drawn to systems of plural polynucleotides, requires structure to analyze multiple polypeptides independently, and is different from Group VI, as the chemical structure is different between polypeptides and polynucleotides, so their structure required would also be different for analysis, Group IX, drawn to antifungal agents, is distinct because they are not required to have any other structure of any other composition.

The methods of inventions I and VIII are patentably distinct. Inventions are patentably distinct if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are not disclosed as capable of use together and require different steps which require different, non-coextensive, considerations. To wit, Group I, drawn to methods of affecting antifungal activity requires administering an agent to a system, while Group VIII, drawn to a screen for candidate compounds requires determining the activity of a target. Because these steps require different structural considerations, the search and examination burden would not be coextensive.

The methods and compositions are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case because either method may use multiple products, e.g., the polynucleotides, the antibodies, or any compound, they are patentably distinct. Moreover, although the antifungal agent of Group IX may be identified by the method of Group VIII, it may also be identified by other methods, e.g., detecting fungus death upon exposure to the compound.

Because these inventions are distinct for the reasons given above and the search and examination required for any particular group is not coextensive with any other group, and because the search and examination burden on the examiner to search and examine any two groups together would be serious, restriction for examination purposes as indicated is proper.

The following Group Restriction is applicable to groups I-V. Therefore, if Applicant elects one of the inventions of Groups I and III-V, they must further restrict that invention to one of the following species.

Claims 1-10 and 13-24 are generic to a plurality of disclosed patentably distinct species comprising 77 patentably distinct target genes, or the proteins encoded therein. Applicant is required under 35 U.S.C. 121 to elect a single disclosed nucleic acid or protein, even though this requirement is traversed.

These target genes are patentably distinct because they have different and structural considerations which must be taken into account. Each of these target genes also have different, non-coextensive structure. Specifically, each target gene encodes different proteins that interact with different molecular mechanisms to effect their purpose and therefore, interfering with any activity of any of these target genes would alter the behavior of the cell's system in a manner which distinct from any other. Moreover, these molecular mechanisms would be non-coextensive, because they interact at different points within the general metabolism of the cells in which they act, and as such would require different sequences.

The following Group Restriction is applicable to groups III and VI-VIII. Therefore, if Applicant elects one of the inventions of groups III or VI-VIII, they must further restrict that invention to one of the following species.

Claims 11-12 and 27-39 are generic to a plurality of disclosed patentably distinct species comprising 77 patentably distinct target genes, or the proteins encoded therein, and the multitude of permutations of such protein/gene in combination with any other(s). Applicant is required

under 35 U.S.C. 121 to elect a single group of disclosed genes or proteins, even though this requirement is traversed.

These target genes are patentably distinct because they have different and structural considerations which must be taken into account. Each of these target genes also have different, non-coextensive structure. Specifically, each target gene encodes different proteins that interact with different molecular mechanisms to effect their purpose and therefore, interfering with any activity of any of these target genes would alter the behavior of the cell's system in a manner which distinct from any other. Moreover, these molecular mechanisms would be non-coextensive, because they interact at different points within the general metabolism of the cells in which they act, and as such would require different sequences.

Applicant is further forewarned that if any particular combination of proteins or genes are chosen, written support for that combination must be provided in the specification in order to avoid a written description/enablement rejection.

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Robert M. Kelly whose telephone number is (571) 272-0729. The examiner can normally be reached on M-F, 9:00am-5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ram Shukla can be reached on (571) 272-0735. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Robert M. Kelly, Ph.D.
Examiner, USPTO, AU 1632
2C55 Remsen Building
(571) 272-0729

DAVE T. NGUYEN
PRIMARY EXAMINER